

Message

From: Aranda, Amber [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2557889D5F134A3DBC525A2DBF6BFDF2-AARANDA]
Sent: 1/21/2022 3:12:00 PM
To: Oakes, Matthew (ENRD) [Matthew.Oakes@usdoj.gov]; Koch, Erin [Koch.Erin@epa.gov]
Subject: RE: FIFRA label change question

Ex. 5 AC/DP

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From: Oakes, Matthew (ENRD) <Matthew.Oakes@usdoj.gov>
Sent: Thursday, January 20, 2022 2:20 PM
To: Aranda, Amber <aranda.amber@epa.gov>; Koch, Erin <Koch.Erin@epa.gov>
Subject: FIFRA label change question

Hi Erin and Amber –

Ex. 5 AC/DP

The relevant quote from the Ninth Circuit decision is below (in red text):

Moreover, EPA permits pesticide manufacturers to make certain changes to labels without prior approval. *See id.* at 623, 131 S.Ct. 2567. Specifically, manufacturers can make minor modifications to labeling without prior EPA approval if EPA is notified of the change. 40 C.F.R. § 152.46(a); EPA, Office of Pesticide Programs, *Pesticide Registration Notice 98-10* (Oct. 22, 1998) (“PRN 98-10”). Thus, unlike the generic drug manufacturers in *PLIVA*, pesticide manufacturers “can act sufficiently independently under federal law” when amending a label. *See PLIVA*, 564 U.S. at 623, 131 S.Ct. 2567.

Though Monsanto contends that “[a]dding a warning about cancer would hardly qualify as a ‘minor modification,’ ” EPA has repeatedly permitted pesticide manufacturers to use the notification procedure to add notices related to cancer to their products’ labels.¹⁰ Nevertheless,

Monsanto ^{*960} counters that there is no “single example where EPA has allowed a registrant to use the notification process” where EPA previously “found the relevant chemical was *not* carcinogenic, much less where it determined a cancer warning would render a label false and misleading,” referring to the 2019 letter.

But neither EPA's 2017 finding that glyphosate is not carcinogenic nor the 2019 letter (which do not carry the force of law) divert Monsanto to a different process for amending a label beyond those normally followed by pesticide manufacturers under FIFRA and its regulations, as described above. Considering the responsibility FIFRA places on manufacturers to update pesticide labels and that EPA has allowed pesticide manufacturers to add cancer warnings to labels through the notification process without prior approval, it is not *impossible* for Monsanto to add a cancer warning to Roundup's label. *See PLIVA*, 564 U.S. at 623, 131 S.Ct. 2567; *see also Wyeth*, 555 U.S. at 573, 129 S.Ct. 1187 (explaining that “[i]mpossibility pre-emption is a demanding defense”).

¹⁰

For instance, pursuant to PRN 98-10, pesticide manufacturer Bayer CropScience notified EPA “of a minor labeling amendment for LARVIN Technical,” informing EPA that “[a]s required by California Proposition 65, the following statement has been added to the label, ‘This product contains a chemical known to the state of California to cause cancer.’” Letter from Larry R. Hodges, Registration Manager, Bayer CropScience, to EPA, Office of Pesticide Programs 4 (Nov. 29, 2012), www3.epa.gov/pesticides/chem_search/ppls/000264-00343-20131217.pdf. In response, EPA's Registration Division “conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10.” Letter from Jennifer Gaines, EPA, Office of Pesticide Programs, to Larry Hodges, Bayer CropScience 2 (Dec. 17, 2012), www3.epa.gov/pesticides/chem_search/ppls/000264-00343-20131217.pdf.

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